EXHIBIT C

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

Master File No. 2:12-MD-02327
MDL 2327
U.S. DISTRICT JUDGE JOSEPH R. GOODWIN

Deposition of ALAN GARELY, M.D., relating to the following cases in Wave 1 of MDL 200:

Carey Beth Cole, et al. V. Ethicon, Inc.
Civil Action No. 2:12-cv-00483
Amanda Deleon, et al. V. Ethicon, Inc.
Civil Action No. 2:12-cv-00358

Rose Gomez, et al. V. Ethicon, Inc.
Civil Action No. 2:12-cv-00344
Donna Zoltowski, et al. V. Ethicon, Inc.
Civil Action No. 2:12-cv-00811

DEPOSITION OF ALAN GARELY, M.D., FACOG, FACS

Friday, April 15, 2016
New York, New York

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with almost all of them.

Q We'll come back to the products in a little bit. Am I correct, Dr. Garely, that you are not an expert in biomaterials?

A Well, I'm familiar with biomaterials, but I'm not a biomaterial engineer.

Q Okay. You're not a polymer scientist, correct?

A That is correct.

Q You're not a trained pathologist, correct?

A That is correct.

Q And you're not board certified in pathology, correct?

A That is correct.

Q You're not trained in neuropathology; is that correct?

A That is correct.

Q And you're not an epidemiologist, correct?

A That is correct.

Q Have you ever been involved in drafting instructions for use for a medical device?

A When -- I've been involved in advising

companies in formulating the instructions for use, but I've actually not physically put the pencil to the paper and written up those instructions myself.

Q Tell me what you have done in advising companies on instructions for use.

A Well, when I was asked to be an expert by Ethicon, back in the late '90s, to come on-board and evaluate the TVT sling, I was sent as part of a group to Sweden and we learned the procedure from the inventors of the TVT procedure.

When we came back to the United States, we were intimately involved in formulating the IFUs to help instruct and educate physicians in the United States on how to use the product.

Q So that was the TVT Retropubic, the original TVT sling?

A Yes, ma'am.

Q As best as you can remember, what was your involvement with respect to the TVT IFU at the time, did you receive a draft of it and review it and provide commentary, what did you do exactly with respect to the IFU?

A It was almost 20 years ago. I just recall that we would have a lot of meetings with the people who were putting the product out. We -- we did everything from educational preparation, educational materials, to helping design the way that the product looked.

We went through different iterations of the needles and the mesh, and we discussed things that belonged in the IFU so that physicians could be properly educated on the use of the product.

Q As you sit here today, can you recall actually reviewing draft versions of the IFU and providing feedback on those draft versions?

A There were so many papers that we were looking at and formulating that to say that I specifically remember any one of those, I can't get my mind around that, no.

Q Dr. Garely, is it fair to say that you do not hold yourself out as an expert in product labeling?

A I don't understand the question.

Q You don't consider yourself an expert in formulating labels for medical devices and

what components those labels need to have?

A I guess I'm not familiar with what a label would be.

Q Fair point. Am I correct that you don't hold yourself out as an expert of what the requirements of the contents of an instructions for use should be?

A Well, I do believe that I'm an expert when it comes to the instructions for use when it applies to products that I'm familiar with, yes.

Q Have you reviewed regulatory guidances or regulations that address what the requirements of device labeling are?

A Only in documents that I reviewed from internal documents of when companies were writing their IFUs and they had background information to go on, but that would have been the only time that I would have reviewed those documents.

Q And what are the documents that you reviewed?

A Whatever -- from this case or from the Bard case, when I had the internal documents

from the companies where they were trying to come up with IFUs and they were talking about the regulatory issues regarding the IFUs, those were the documents that I saw.

Q Have you ever reviewed FDA regulations relating to labeling and what needs to go into product instructions for use?

A I don't know that I've specifically seen that document.

Q Have you ever reviewed the document that is known as the FDA Blue Book Memo on what needs to go into instructions for use?

A That one sounds familiar. I just don't recall having -- what I would have read in it. But it does sound familiar.

Q It sounds familiar to you, but as you sit here today, you're not sure whether or not you've looked at that particular document?

A Correct.

Q Have you ever reviewed Ethicon's standard operating procedures regarding what information needs to go into instructions for use?

A I don't know if I've looked at that

manual, only what I've seen from the internal documents and discussion of what should be included and excluded from the IFU.

Q Okay. As you sit here right now, you can't recall looking at a particular Ethicon labeling standard operating procedure, SOP document, that lays out what needs to be in an instructions for use, correct?

A Based on the internal documents that I read, I don't even know if such a thing existed because they were choosing to exclude information that would have helped physicians to use the product better.

So if there was some guideline, some guideline that would have told them what to do, I don't know that they followed it. Apparently they just chose indiscriminately to include or exclude information that could have or could not have been helpful to physicians.

MS. KABBASH: Move to strike as nonresponsive.

BY MS. KABBASH:

Q My question, Doctor, is as you sit here today, am I correct that you do not recall

reviewing a particular Ethicon standard operating procedure document related to what should go in labeling?

A I don't recall.

Q Am I correct that you are not an expert in design control procedures and requirements for bringing a product through development?

A I don't know what you mean by "design control."

Q So there are various FDA regulations and requirements that govern a company's process of bringing a product through the design stages, and eventually to market, they're called design controls. And are you familiar with FDA regulations that govern what a company must accomplish in their design controls?

A Only from my participation in products coming from the drawing board to marketing. That's my only experience with that.

Q And you would not hold yourself out as an expert in FDA regulations on design controls, correct?

A That would be correct.

Q You would not be able to speak to how,

assessments or -- are you familiar with what an FMEA or a DDSA is; do you know what those documents are?

A I'm not good on the acronyms. Could you tell me what they stand for?

Q I will try. Design Device Safety Assessment. I need to remind myself what an FMEA is, Failure Mode Effects Analysis. Are you familiar with what those documents are and what purpose they serve within a company's design control processes?

A I do and I am.

Q Have you had involvement in the preparation of those documents?

A I believe that I was involved in the preparation of those documents for a device.

Q Which device was that?

A I think I was involved in that for the device of ligature made by -- at the time I think it was U.S. Surgical and I think it was acquired or changed its name to Covidien.

Q And what type of device is that?

A It's a device that -- it grabs tissue, it seals the tissue with heat, and then it cuts

the prolapse.

It's not a very elegant operation and the success rates were not very good.

Q How many times have you used biologic grafts to treat prolapse?

A Innumerable, I could not venture a guess. I used them for probably two or three years on multiple cases.

Q Do you still use them today?

A Not as a -- not as a material to -- for prolapse. I use them for -- to help with healing.

Q Which biologic grafts have you used?

A I used -- what was the name of that one. It encapsulated -- it was like a porcine dermis. It was --

MR. MATTHEWS: Who made it?

THE WITNESS: I think it was made by Bard.

MR. MATTHEWS: Pelvicol?

A Pelvicol, thank you. I used Pelvicol a lot. I used Surgisis. There were -- there were a few others. I just don't remember. It's been such a long time since I've used biologics, it's

Q Sofradim?

A Sofradim. And I put that mesh into a patient once.

Q I take it it didn't go very well?

A It went well. But I developed a -- I put the one in and then I wanted to see how the patient would do and the patient developed an erosion. And I also had used Marlex at some point when I was just finishing my fellowship in 1995, I used Marlex on a few patients and I didn't like the way that it healed. It was too hard.

Q Both the IntePro and the Caldera mesh are made of polypropylene, correct?

A Correct.

Q And is it fair to say that you've used IntePro and the Caldera product thousands of times?

A That would be correct.

Q So between the -- your use of Ethicon's Prolene mesh, I think you said some limited use of the Prolene Soft mesh, your use of Caldera's product and IntePro, fair to say that you have implanted a polypropylene graft to treat

abdominal sacrocolpopexy in thousands of women, correct?

A That's correct.

Q And that's going back to your fellowship, correct, or even to your residency?

A Oh, no, I did not use these devices in residency.

Q Okay.

A Since fellowship, yes. But the majority clearly -- my fellowship was two years. The majority of these cases were not as a trainee, but as an attending physician.

Q So you clearly believe that polypropylene is an appropriate graft to use to treat prolapse in an abdominal approach, correct?

A Correct, in an abdominal approach.

Q Doctor, let me try in a sense to sort of cut to the chase on one particular issue. Is it your opinion that the polypropylene is fine to use to treat prolapse, but it should not be used in a transvaginal approach; is that -- if I had to kind of boil down your opinion, is that what your opinion is?

doing with Boston Scientific?

A And the IVS Tunneller.

Q So you did use the IVS Tunneller to treat an anterior defect?

A Not anterior, you said apical.

Q I apologize, I misspoke. Have you ever used transvaginal mesh to treat an anterior defect?

A When I used the Prolene mesh on the device with Boston Scientific, we were also using it to treat anterior defects.

Q Am I correct that you have never implanted Gynemesh PS transvaginally in any women?

A I think you're correct.

Q You've never implanted the Prolift, correct?

A I've never implanted the Prolift.

Q And you've never implanted the Prolift+M, correct?

A Correct.

Q You've never implanted Bard's Avaulta?

A Correct.

Q You've never implanted AMS's Elevate?

A That's correct.

Q Have you ever looked at a piece of Gynemesh PS under the microscope?

A No.

Q Have you ever looked at a piece of Prolift+M under the microscope?

A Well, I'd like to just add to that in that I've not physically put the mesh under the microscope, but I have papers that I have reviewed that have pictures of the material under the microscope, so I've looked at photographs of microscopic material, but I've never actually physically taken the mesh and put it under the microscope myself.

Q You've not performed benchtop testing on Prolift or Gynemesh PS mesh or tools, correct?

A Correct.

Q And you've not performed benchtop testing on Prolift+M mesh or tools, correct?

A Correct.

Q You have not performed animal studies on Prolift or Gynemesh PS mesh, correct?

A Correct.

radiologist, was at my center at Winthrop, where I was based, and I went between Winthrop and Sinai, but I sat with Jonathan and looked at a lot of the images with him, but he did all the interpretations.

Q Doctor, if you could turn to your report for Prolift, which is Exhibit 2. And turn to page 6.

A Okay.

Q Doctor, on page 6 under opinion 2A, you opine that Ethicon brought these products to market without FDA 510(k) clearance, correct? Do you state that opinion there?

A I do.

Q And by "these products," I understand that you mean the Prolift kits, the different iterations of the Prolift kit?

A That's correct.

Q Am I correct that you've never worked at the FDA?

A That is correct.

Q Am I correct that while you may have some familiarity with the 510(k) process, you don't hold yourself out as an expert in the

510(k) clearance process, correct?

A Correct.

Q You're not an expert on FDA regulations, correct?

A I'm not a regulatory expert, correct.

Q Have you ever reviewed a company's 510(k) submission to the FDA before you became an expert in mesh litigation?

A I have worked as an industry consultant on and off for the last 25 years. There have been products where things were coming to market and as part of an advisory group, I have looked at the 510(k) applications. I don't know specifically which products those would have been, but I have seen the applications.

Q Have you ever provided feedback to the company submitting the 510(k) applications on the content of the application and what should or should not be in it?

A Well, I know that when I reviewed some of these before they were submitted -- and I wasn't just by myself, it was usually with a group of people, and we would look at these. There were times when we would make suggestions

if we thought things needed to be added. I don't know that I ever said something should have ever been omitted.

Q You made suggestions on additions to make to the 510(k) application itself?

A Correct.

Q And what product or submission was that?

A I have been part of these groups on so many products, I don't specifically remember because it wasn't something that I would have ever thought I would have needed to remember. I just remember looking at the binders. I'm trying to think.

Q Let me ask you, when was the last time you recall providing such feedback?

A It would have been before 2003.

Q So it would have been at least 13 years ago that you would have provided such feedback, correct?

A Correct.

Q Have you ever reviewed the FDA guidance document on when to submit a 510(k)?

A I don't recall.

Q Have you ever reviewed Federal statutes or regulations on whether a product is misbranded or adulterated?

A I do not recall.

Q As you sit here today, is it fair to say that you don't have an understanding of what Federal statutes or regulations address misbranding or adulteration of products?

A Not today, no.

Q Am I correct that you will not be offering opinions at trial regarding whether Ethicon complied with FDA requirements or regulations in its sale of Prolift or in its labeling for Prolift?

A Just what I put in my expert report on 2A.

Q You indicate here that Ethicon brought Prolift to market without FDA 510(k) clearance, correct?

A That is correct.

Q Am I correct that --

MR. MATTHEWS: I can state in my place that he will not be offering an opinion on that at trial. You can ask him about it all you

want.

MS. KABBASH: On 2A?

MR. MATTHEWS: 2A.

MS. KABBASH: Okay. I will rely on that representation.

BY MS. KABBASH:

Q Dr. Garely, would you agree with me that there is no transvaginal mesh kit to treat prolapse that has been the subject of more studies than Prolift? Would you agree with that?

A I have not done an independent research into the other mesh kits for me to be able to say that Prolift has had the most amount of research. I cannot say that.

Q So as we sit here today, you don't know whether that's true or not?

A Not to my -- not to my memory.

Q Do you know if Prolift has more RCTs in particular studying it than other manufacturers' mesh kits?

A I have not delved into the research of the other mesh kits. I cannot say.

Q So you have not studied the quality and

recall that?

A Well, there were so many different iterations of the pore size based on whether it was at rest or whether it was at stretch or tension or whether -- the axis of the stretch occurred. So know that greater than 1 millimeter was good and 2.4, that was better than 1, but there was a distortion of the pores that occurred, once the tissue was implanted -- once the material was implanted into the tissue.

Q On what are you basing your opinion that there was a distortion of the pores that occurred? What body of information is that opinion based on?

A It's in my -- somewhere in my report, but it was based on internal documents from research that I had looked at that was done by Johnson & Johnson.

Q Okay. Are you pointing to any -- besides company documents, which you've just discussed, is there any medical literature that you can specifically point me to that concludes that the pores in Prolift mesh deform or distort?

A Yes.

Q Which study?

A Well, I cite different papers in my footnotes in different parts of this paper.

Q Where are you?

A I'm on page 12. And talking about excessive scarification and shrinkage, when there's shrinkage, there's a decrease in the pore size. That's reference 22.

Q Reference 22 is to Ethicon cadaver labs, correct?

A That reference for that point.

Q But my question is, can you point me to a study piece -- a published -- peer-reviewed published medical literature?

Let me ask a more precise question. Can you point me to any peer-reviewed published medical literature that has concluded that the pores in Ethicon's Prolift mesh collapse or deform to be less than 1 millimeter?

A Well, the -- there's the same mesh that was used on abdominal hernia repairs demonstrated shrinkage. I don't -- I'd have to see the papers right in front of me to recall

whether or not they said that the pore size actually shrunk. I need a minute to just take a look.

Q Why don't we go off the clock for a second, and you can take a look to find it.

A Okay.

(Whereupon, a brief recess is taken.)

THE WITNESS: Okay.

BY MS. KABBASH:

Q Okay?

A What I was relying on was the internal documents from Ethicon which are cited as number 6 and number 7. Those would be --

Q I apologize. What page are you on?

A It would be page 9. The top paragraph number 3 with reference number 6 and reference number 7. Those were internal documents done by Ethicon.

So off the top of my head, no, I cannot cite a published paper, but Ethicon knew from their own internal research that the pores did shrink down to less than 1 millimeter.

Q Okay. So just to make the record

clear, as we sit here right now, you cannot point me to a piece of published medical literature which concludes that the pore size of Prolift mesh deforms to less than 1 millimeter, correct, as we sit here right now?

A Well, there's -- I mean, I don't have my PubMed in front of me, but if I'm -- and I don't know that I can recall specifically that Klausterhoffen made a note about pore size. But I think that one of his papers did discuss shrinkage of pore size, but I can't be a hundred percent certain without looking at the paper.

Q And you have not cited that paper in your report, correct?

A I don't think I did.

Q Okay. You also have -- let's go to page 11 of your report, which I think we're already here. Opinion number 6, you say, "As the Prolift mesh scars in, the resulting shrinkage or contracture of the tissues surrounding the mesh can entrap nerves, deform the vagina and pelvic anatomy," et cetera. And then you go on to say below that, you discuss nerve entrapment with chronic pain. Do you see

that?

A I do.

Q You say sometimes after one year there are no complaints and then complaints happen -- oh, I'm sorry, you're quoting something here, an Ethicon surgeon panel meeting, and it goes on to say, "Often the result of tiny nerves in the granuloma and that's just a matter of" -- strike that.

In this opinion, you were making -- you were opining that patients may suffer complications from tiny nerves that get entrapped in the mesh, correct?

A I was opining that I agreed with Ethicon's surgeon panel's assessment. I was agreeing with them.

Q And that opinion is that tiny nerves can get entrapped in the mesh due to contraction, correct?

A Yes.

Q Okay. And you also hold this same opinion with respect to Prolift+M, correct?

A I do.

Q Okay. Would you agree that the

and the pain got better, you would deduce or make an assumption that there were nerves in the mesh, correct?

A That's fair.

Q To actually investigate the explants and see if there is evidence of nerves in the mesh, you would have to take that mesh, put it on a slide, and put it under a microscope and look at it, correct?

A Well, it's a matter -- it's a point of semantics, but yes, if you wanted to actually prove it, it's not something that's done in common practice.

Q I think plaintiff's expert pathologist might disagree with that, but...

Am I correct that you were not trained in interpreting what can be viewed on explant slides under a microscope? In other words, not only have you not put a mesh slide under a microscope and looked at it, even if you had, you are not trained in how to interpret what you're seeing on that slide; is that correct?

A Just from what I know from basic histology and pathology in medical school. And

I did do two months of pathology as a resident as well.

Q And that was about 20 years ago?

A I did that probably -- I did that rotation in my second year of residency, that was 1990.

Q Is it fair to say that if you -- if we had a mesh that was on a slide and it got put under the microscope, you would need the assistance of a pathologist to be able to properly and reliably interpret what was on that mesh slide, correct? Or some other professional with a background other than yours?

A I could probably muddle through it on the bigger structures, but I would have a problem on the smaller things.

Q Tiny nerves in particular, correct?

A I'm not really good at looking at tiny nerves under the microscope.

Q You don't typically use a microscope to make treatment recommendations and decisions for your patients, correct?

A I do not.

Q And you don't use a microscope in order

to assess how to treat complications if you have patients with complications, correct?

A I do not.

Q Do you know which stains need to be used so that nerves can be seen on a mesh slide under a microscope?

A I know for a fact that I used to know the answer to this, but as I sit here today, I do not recall.

Q Okay. Do you know what level of magnification needs to be used so that nerves can be viewed in a mesh explant?

A Now I feel bad that I didn't pay more attention in pathology. I do not recall.

Q Okay. If we move to page 12 -- I'm coming to a good stopping point soon, I'm just trying to get there. I'm not trying to starve you or anything, believe me.

As we come to page 12 of your report, you have opinion number 7, and in the second paragraph of opinion 7 or paragraph 7, you say, "As the parts of the mesh arms of Prolift kits incorporate into tissue via a scarring process, they pull asymmetrically on the center mesh

Q Am I correct, Doctor, that in this opinion, regarding the asymmetrical pulling on the arms and the roping and curling opinion, that in your report as you articulate these opinions, you have not relied on peer-reviewed medical literature to support these opinions?

We've just discussed the cadaver lab that you just mentioned. We've discussed your experience with the 10 to 20 explants. Am I correct that in support of your roping and curling opinion and your asymmetrical pulling opinion, you are not relying in this report on peer-reviewed medical literature, correct?

A I don't -- I don't know what else to call it when the -- when the arms rope and curl, other than roping and curling.

MS. KABBASH: Move to strike.

BY MS. KABBASH:

Q You have not cited in your report on these two points any peer-reviewed medical literature that supports your opinions on roping, curling and asymmetrical pulling, correct?

A I don't know that it's not included in

any of the references that I've put forth into my expert report, but off the top of my head, I can't recall a specific paper where they noted roping and curling.

Q Okay. Why don't we break for lunch.

(Whereupon, a luncheon recess is taken.)

MR. MATTHEWS: He'll read and sign.

BY MS. KABBASH:

Q Dr. Garely, we took a break for lunch. Are you ready to proceed?

A Yes, ma'am.

Q Dr. Garely, will you be offering an opinion at trial to a reasonable degree of medical certainty that polypropylene mesh degrades after implantation in the body?

A Only what I've referenced in my expert report.

Q You've referenced in your expert report -- you have a paragraph on page 23 that there's a statement in the IFU, "The material in Gynemesh is not absorbed nor is it subject to degradation or weakening by the action of tissue enzymes is contradicted by Ethicon internal

documents and reports which clearly show that the material was subject to degradation inside the body."

That's what your statement in your report is, correct?

A Correct.

Q So is your opinion that the line in the IFU is contradicted by Ethicon's internal documents?

A I'm not saying that it's contradicted. I'm just saying that it's not substantiated by the documents that I reviewed based on the internal -- the internal documents from the company.

Q And what documents are those that you reviewed?

A It's reference 39.

Q And in reference 39, you reference a series of internal Ethicon minutes and PowerPoint documents and internal memos, correct?

A Correct.

Q And that is the basis for your opinion that you -- we just discussed about the line in

the IFU about degradation, correct?

A That's my basis of opinion.

Q Okay. There -- you have not cited in footnote 39 any medical literature, peer-reviewed medical literature to support your opinion, correct?

A Correct.

Q I have to ask the question again, sir. Am I correct that at trial you will not be opining to a reasonable degree of medical certainty that polypropylene mesh degrades within the body? Let me strike that.

Is it your opinion to a reasonable degree of medical certainty that polypropylene mesh degrades within the body? Do you believe that?

A I believe it has possibly -- I don't think the degradation related to the mesh is the major part of why this mesh is problematic.

Q Okay. I appreciate that, but that wasn't my question. My question is, do you have an opinion to a reasonable degree of medical certainty that polypropylene mesh degrades within the body? That is not one of your

opinions, is it, Doctor?

A No, it's not.

Q Certainly if you believe that, you wouldn't have implanted thousands of retropubic slings into women, correct?

A Correct.

Q Okay. So your sole opinion with respect to degradation is that the statement in the IFU that we just discussed is not supported by the internal company documents that you cite in footnote 39, correct?

A I'm sorry, repeat that question.

MS. KABBASH: Sure. Can I ask you, Dana, to repeat it?

(Whereupon, the question is read back by the reporter.)

A Correct.

Q Doctor, on page 29 of your report, and you're welcome to refer to it, you opine that Ethicon had at its disposal a number of safer feasible alternative designs that could have been utilized instead of the Prolift kits, correct?

A That's correct.

not have mesh arms and does not involve the use of trocars?

A Yes.

Q But you did not ever try Prosima, correct?

A I did not.

Q And you have not reviewed in preparation -- strike that.

You have not reviewed the medical literature addressing Prosima in preparing your opinions in your report, correct?

A That's correct.

Q You also mention polyvinylidene fluoride, and then you have in parentheses, PVDF/PRONOVA. What is PVDF and what is PRONOVA, are they the same thing or different things?

A PVDF is the basis of the PRONOVA mesh.

Q Is PRONOVA a mesh?

A It's a mesh.

Q Where is PRONOVA -- is PRONOVA available --

A I don't believe it is available. It's available to -- internally to the company that makes it, which is Johnson & Johnson, but I

don't believe at this time that it's commercially available.

Q Am I correct that you are not aware -- strike that.

Am I correct that FDA has never cleared or approved PRONOVA for use in the United States to treat pelvic organ prolapse; is that correct?

A I don't know for a fact, but I believe it is correct.

Q Am I correct that FDA has never cleared PVDF mesh for use in the United States to treat prolapse?

A I don't believe so.

Q Have you ever used PVDF or PRONOVA mesh?

A I have not.

Q Have you ever -- to your knowledge, are there any studies published in the medical literature about the use of PVDF or PRONOVA for pelvic organ prolapse repair?

A I think the only literature I reviewed regarding PVDF was based on internal documentation from Johnson & Johnson.

Q Am I correct, Dr. Garely, that your

opinion proposing PVDF/PRONOVA as a proposed alternative design is based solely on company documents that you have reviewed in your role as an expert?

A Yes.

Q So if there is -- so fair to say you have not reviewed any medical literature on the application of PVDF in a hernia application, correct?

A That was not something that I was looking at, no.

Q And am I correct that you have not reviewed any medical literature assessing PVDF or PRONOVA in an indication -- or let me start that over again.

You have not reviewed any medical literature assessing PVDF or PRONOVA to treat pelvic organ prolapse, correct?

A I only mentioned it because the internal documentation showed that -- that Ethicon's own people were considering this as an alternative because they thought it was a better material. That's the only reason that I included it in here, was I followed the guide

from Ethicon.

Q But you are not aware of any clinical studies that actually assess whether PVDF or PRONOVA would be safe and effective when used to treat prolapse, correct?

A Correct.

Q You're not aware of any such data, right?

A Correct.

Q And am I correct that your opinion on PVDF or PRONOVA as an alternative design is based on your inferences of what Ethicon knew about PVDF?

A It wasn't so much of an inference as it was just restating what was stated in the internal documentation, which was they, the people in the documents that were provided to me, had opined that they thought PVDF would be a better alternative than polypropylene.

Q Isn't it correct that the people at Ethicon who were discussing that were considering PVDF as an alternative as they consider lots of materials as alternatives -- well, strike that. Am I correct

honor code, your own belief system.

Q The J&J credo is not a regulatory standard, correct?

A They -- it's their credo. If they state it, then they should live to the -- to their credo, then why state it?

Q I appreciate that. But my question is, can you point to any Federal regulation, guidance or other type of objective standard that requires Ethicon's IFU to include frequency, severity, duration and permanence information? Can you point to such a standard?

A As I sit here right now, I cannot point to it.

Q Would you agree with me that the 2009 version of the Prolift IFU did include frequency information because it reported the results of the -- one-year results of the French and U.S. TVM studies?

A I would have to see the IFU because I don't recall the different iterations of it, but if you're telling me that's what it said, I will believe you and I would have no reason to doubt that to be true.

every sentence in the entire thing. But I chose to sort of not clog up the entire paper, my expert report, with a thousand references. I tried to use references that I thought were more applicable to the thought process of each section in general. So I don't know that there was anything specific in this report that would have helped me support my position.

Q Am I correct that you didn't have -- play any role in the generation of this document, correct?

A No.

Q Okay. You were not one of the surgeons that was consulted or attended the user forums from which this information came about, right?

A If I was, I have no memory of it.

Q Okay. If you look to your report -- Doctor, would you implant PVDF transvaginally in one of your patients?

A I would not.

Q You would not?

A Not based on not knowing clinical data on the product, I would not, or unless I

participated in a study for the product.

Q That would be -- clinical data on that product would be the prerequisite for you to consider implanting PVDF in one of your patients, correct?

A Clinical data in the vagina, correct.

Q Doctor, have you ever seen an IFU for a transvaginal mesh implant to treat POP that you concluded was adequate?

A I don't know. I never looked at an IFU with that eye. I would have to have all the IFUs in front of me, read through them and make that assessment. I can't do that right now.

Q You've reviewed Bard IFUs?

A I have.

Q Have you reviewed IFUs of any other manufacturers?

A I reviewed -- for pelvic organ prolapse?

Q Yes.

A Or for incontinence?

Q For pelvic organ prolapse.

A For pelvic organ prolapse, I've looked at the Apogee and the Perigee IFUs. I have not

A Well, it's always -- it's always a tough question to ask a physician, is this going to be a permanent condition? Well, it's only permanent until you cure it. It's not permanent if you cure it. As long as it's ongoing, it's permanent unless -- as long -- if the patient died today and the patient had the problem, that was considered permanent.

So if you're asking me on a followup study of a year or two years, can they make an assessment about permanency, it can be implied if patients don't get better that are in the study. I can speak for myself as a doctor who takes care of many of these patients that despite multiple removals of the mesh, these patients have chronic and ongoing dyspareunia and chronic pelvic pain that, in my opinion, barring some miracle, they're going to have permanency of their complaints.

Q Am I correct that your opinion that patients' injuries, including dyspareunia and pelvic pain, is permanent, because that's one of your opinions, that that is based on what you've seen in your practice and not based on any

particular piece of medical literature that you've relied upon?

A Well, every paper that I've cited in my expert report that has followed patients out, I don't know that any of those patients that have -- any of those papers that have followed patients for more than two years have ever said, and by the way, we had all the patients in this study that had pelvic pain and dyspareunia, 100 percent of them have had resolution of their symptoms, given if the paper were powered appropriately. Obviously if the paper had a small number of patients, there's a statistical chance that some of them in that paper may experience resolution. But I'm saying that among -- the discussions that I have among my peers at professional society meetings and among patients that I see in my practice and patients that are seen in other practices that specialize in the repair of transvaginal mesh complications, I can say with a hundred percent certainty that there are some patients in this -- in my practice that will go on to have lifelong dyspareunia and pelvic pain

because they've already seen four or five other doctors and have had four or five operations to try to relieve the pain and nothing seems to work.

I'm not saying I would give up on them and say, okay, you now have permanent pelvic pain, you have to live with it for the rest of your life and we're just going to accept that. I refuse to do that.

I am always looking for something to help and alleviate the chronicity of pain that my patients experience. I -- I -- that's one of my things that is sort of a hallmark of our practice, that we try not to give up on anybody.

Q You are not relying on any peer-reviewed medical literature or any medical literature to support your conclusion that pelvic pain and dyspareunia following Prolift is permanent and not treatable, correct?

A Anything that's published in the literature regarding patients is just someone else's experience with their patients. That's all they're reporting. They're reporting in their experience, this is how our patients did.

I can tell you that without publishing my experience on these patients, that I have patients who have permanent disability up until this point that I don't know if it will get better. So if you're asking me is there a publication that says that these patients are going to get better?

No, there's no paper that's going to say that these patients are going to get better, just like there's no paper that has said we can predict with 100 percent certainty that every one of these patients is going to have lifelong pain. I don't really -- I'm telling you that there are patients that are going to be plagued with pain for the rest of their lives, barring a miracle. That's the best I can do.

Q And your opinion about that is based on what you've seen in your patients, correct?

A In a very large -- one of the largest pelvic surgery practices in the country.

Q Your practice, correct?

A My practice.

Q I just realized, I never marked your reliance lists. Let's do that.

CERTIFICATION

I, DANA N. SREBRENICK, a Notary Public for and within the State of New York, do hereby certify:

That the witness, ALAN GARELY, M.D., FACOG, FACS, whose testimony as herein set forth, was duly sworn by me; and that the within transcript is a true record of the testimony given by said witness.

I further certify that I am not related to any of the parties to this action by blood or marriage, and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 18th day of April 2016.

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DANA N. SREBRENICK, CLR, CRR

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